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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,494	11/20/2001	Tianmei Ouyang	LIFE040	8555

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,494	OUYANG ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10,33 and 43-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,33,43-48,50 and 51* is/are rejected.

7)☒ Claim(s) *49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4,6,7/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 06042004
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination, amendment and declaration filed June 17, 2004 has bee received and entered into the case. Claims 3, 35 – 42 have been canceled; claims 43 – 51 have been added; claims 1 – 2, 4 – 10, 33 – 34 and 43 – 51 are pending and have been considered on the merits. All arguments and submissions have been fully considered.

Claim Objections

Claim 49 is objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, first paragraph, have been withdrawn due to amendment.

Rejections under 35 U.S.C. 112, second paragraph have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 – 2, 4 – 5, 8 – 9, 33 and 50 – 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon Chemiphar.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent at a concentration of about 1 – 25 mM. The flavin agent is FAD, and the composition is a fluid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17; the dye is present at about 1.5 – 50 mM; and the phenazine electron transfer agent is present at about 0.01 – 50 mM.

Nippon teaches a liquid reagent composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

Nippon does not teach the compositions with the claimed amounts, concentrations or ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in

the art would have been motivated by routine practice to optimize the reagents of Nippon with a reasonable expectation for successfully obtaining an effective reagent composition.

4. Claims 1 – 2, 4 – 10, 33 and 50 – 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouyang.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent present at about 1 – 15 mM. The flavin agent is FAD, the phenazine agent is PES, and the composition is dry or wet. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17; the tetrazolium dye is present at about 1.5 – 50 mM; and the phenazine is present at about 0.01 – 50 mM.

Ouyang teaches a reagent composition comprising a tetrazolium dye, FAD (coenzyme factor), oxidases and/or dehydrogenases and PES (p.4 – 5). The composition is wet or dry (p.5 0036).

Ouyang does not teach the compositions with the claimed amounts, concentrations or ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Ouyang with a reasonable expectation for successfully obtaining an effective reagent composition.

5. Claims 1 – 2, 4, 6, 8, 33, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinbach.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent present at about 1 – 25 mM. The flavin agent is FAD; and the composition further contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17; the tetrazolium dye is present at about 1.5 – 50 mM; and the phenazine is present at about 0.01 – 50 mM.

Steinbach teaches reagent compositions comprising tetrazolium salts (col.4 line 44-59), PMS (phenazine electron transfer agent) (col.6 line 28-30), FAD (col.4 line 28-33), diaphorase (dehydrogenases) (col.6 line 28-30, col.3 line 22-28), and NAD (enzyme cofactor) (col.4 line 28-32).

Steinbach does not teach the compositions with the claimed amounts, concentrations or ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Steinbach with a reasonable expectation for successfully obtaining an effective reagent composition.

6. Claims 1 – 2, 4 – 10, 33 – 34, 43 – 48 and 50 – 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouyang and Geisler.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent present at about 1 – 15 mM. The flavin agent is FAD, the phenazine agent is PES, and the composition is dry or wet. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17; the tetrazolium dye is present at about 1.5 – 50 mM; and the phenazine is present at about 0.01 – 50 mM. The reagent further comprises a Group IIIA compound that is present at about 0.1 – 1.2 M, is a boron compound or boric acid. The Group IIIA and dye are present at a ratio of 50 – 800 and the compound and flavin are at a ratio or about 2 – 800.

Ouyang teaches a reagent composition comprising a tetrazolium dye, FAD (coenzyme factor), oxidases and/or dehydrogenases and PES (p.4 – 5). The composition is wet or dry (p.5 0036).

Geisler teaches fluid and powder reagent compositions for diagnostic use, the compositions comprising tetrazolium salts, boric acid, dehydrogenases and NAD (enzyme cofactor) (col.1-4).

The references do not teach the compositions with the claimed amounts, concentrations or ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Ouyang and/or Geisler with a reasonable expectation for successfully obtaining an effective reagent composition.

The references do not teach the reagent compositions wherein both a Group IIIA compound and a flavin stabilizing agent are used. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the diagnostic reagents for their common use, as disclosed by the cited references above. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully obtaining an effective reagent composition.

Response to Arguments

Applicant argues that the references do not teach the amounts or ratios of the ingredients as claimed and provides a declaration by the inventor who reiterates the same arguments.

However, these arguments fail to persuade for the reasons set forth above. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of the cited references with a reasonable expectation for successfully obtaining an effective reagent composition. Regarding the declaration, applicant merely reiterates the arguments made in the response and fails to provide a showing of any unexpected result or advantages of the claimed composition compared to those of the prior art. Absent evidence of unexpected results or advantages, the claims stand obvious for the reasons here and above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
July 21, 2004.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER